UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

LINDA HALL and HOWARD HALL,	)	
	)	
Plaintiffs,	)	
	)	**No. 1:19-cv-193 SNLJ**
vs.	)	
	)	
ETHICON, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter was originally filed on a short-form complaint in *In re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327 (S.D. W. Va.), on February 19, 2013. The case was transferred to this Court on October 30, 2019, and assigned to the undersigned on November 12, 2019. Defendants Johnson & Johnson and Ethicon, Inc. have moved for partial summary judgment (#23).

I. Background

Plaintiff Linda Hall underwent implantation of the defendants' product—Gynecare Prosima mesh—at Perry County Memorial Hospital on June 14, 2011. Dr. Lois Jensen performed the procedure to treat plaintiff's diagnosis of symptomatic cystocele. Dr. Jensen testified that she followed the Instructions for Use ("IFU") and followed good surgical principals and guidelines. However, plaintiff developed complications, including mesh erosion, vaginal pain, vaginal bleeding, dyspareunia, and recurrent cystocele. She underwent two revision surgeries performed by Dr. Dionysios Veronikis at Mercy Hospital in St. Louis, Missouri. The second surgery involved a sacrospinous

colpopexy, enterocele repair, cystocele repair, anterior colporrhaphy, rectocele repair, posterior colporrhaphy, and colpoperineorrhaphy, and a new "Caldera Medical Desara Sling System" was implanted. Despite those procedures, plaintiff's symptoms including dyspareunia persist.

Plaintiff filed this lawsuit claiming that defendants' product, Prosima pelvic mesh, was defective and had caused her injury. Plaintiffs' complaint included eighteen counts. Plaintiff has abandoned numerous claims. Defendants have moved for summary judgment on several claims, but plaintiffs oppose summary judgment on only two claims: Count I for negligent failure to warn, and Count III for strict liability failure to warn. Notably, defendants have not moved for summary judgment on negligent design (Count I), strict liability design defect (Count V), loss of consortium (Count XVI), punitive damages (Count XVII), or discovery rule and tolling claim (Count XVIII)

Plaintiff's expert, Dr. James M. Wheeler, MD has reviewed the medical records, performed a differential diagnosis, and authored an expert report.

II. Legal Standard

Pursuant to Federal Rule of Civil Procedure 56(c), a district court may grant a motion for summary judgment if all of the information before the court demonstrates that "there is no genuine issue as to material fact and the moving party is entitled to judgment as a matter of law." *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 467 (1962). The burden is on the moving party. *City of Mt. Pleasant, Iowa v. Assoc. Elec. Co-op., Inc.*, 838 F.2d 268, 273 (8th Cir. 1988). After the moving party discharges this burden, the nonmoving party must do more than show that there is some doubt as to the facts. *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Instead, the nonmoving party bears the burden of setting forth specific facts showing that

there is sufficient evidence in its favor to allow a jury to return a verdict for it. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986).

In ruling on a motion for summary judgment, the court must review the facts in a light most favorable to the party opposing the motion and give that party the benefit of any inferences that logically can be drawn from those facts. *Buller v. Buechler*, 706 F.2d 844, 846 (8th Cir. 1983). The court is required to resolve all conflicts of evidence in favor of the nonmoving party. *Robert Johnson Grain Co. v. Chem. Interchange Co.*, 541 F.2d 207, 210 (8th Cir. 1976).

The parties agree that Missouri law applies.

III. Discussion

Plaintiffs oppose summary judgment on two claims: Count I for negligent failure to warn and Count III for strict liability failure to warn. Each is discussed below.

A. Strict Liability Failure to Warn (Count III)

Defendants contend they are entitled to summary judgment on the strict liability claim for failure to warn because plaintiff's implanting physician, Dr. Jensen, testified that a different warning would not have changed her decision to use the product.

A plaintiff alleging failure to warn must establish causation by showing "that a warning would have altered the behavior of the individuals involved…." *Moore v. Ford Motor Co*., 332 S.W.3d 749, 762 (Mo. *banc* 2011) (internal quotation omitted); *Tune v. Synergy Gas Corp*., 883 S.W.2d 10, 14 (Mo. *banc* 1994). In cases involving medical devices, Missouri courts apply the learned intermediary doctrine, which requires a

manufacturer to properly warn the doctor of the dangers involved. *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146 (Mo. 1967); *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985). Plaintiffs claim that defendants failed to warn her doctor, Dr. Jensen, of the known dangers associated with Prosima mesh, and that, if Dr. Jensen had known about the risks, she would not have implanted that mesh for plaintiff.

Defendants note that Dr. Jensen testified that she stands by her decision and that additional risk information would not have changed her decision to use the product. Defendants thus argue plaintiffs cannot meet their burden of demonstrating that a different warning would have changed Dr. Jensen's decision.

Plaintiffs respond that Dr. Jensen also testified that she would have given her patient "as many details as possible" about the proposed implant, including the statistics regarding complications. Dr. Jensen would have wanted to know if the IFU had contained inaccurate information, for example, that there was not a rare risk but a common risk of chronic or severe infections, or that there was a 19.6% risk of painful mesh shrinkage. Dr. Jensen testified she would have passed those statistics on to plaintiff. Plaintiff testified that, if she had been given the additional information about the severity and permanence of risks, she would not have gone through with the surgery. Plaintiff thus insists summary judgment is inappropriate for her failure to warn claim.

The defendants filed no reply brief. Because it appears that there is a disputed issue of fact regarding whether a different warning would have changed whether Dr. Jensen used the mesh on plaintiff, the Court cannot grant summary judgment to defendants on the strict liability failure to warn claim.

B. Negligent Failure to Warn (Count I)

As for the negligent failure to warn claim, the same analysis applies regarding causation. The Court will deny the motion for summary judgment as to the negligent failure to warn claim.

IV. Conclusion

Summary judgment will be granted to defendants on Counts II, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, and XV. Summary judgment will also be granted to defendants on Count I, to the extent it alleges a negligent manufacturing defect claim. Summary judgment is denied as to Count I to the extent it alleges a negligent failure to warn claim and as to Count III.

Remaining claims in this matter are thus Count I to the extent it alleges a negligent failure to warn claim, Count I to the extent it alleges a negligent design defect, and Counts III, V, XVI, XVII, and XVIII.

Accordingly,

IT IS HEREBY ORDERED that defendants' motion for summary judgment is GRANTED in part and DENIED in part.

IT IS FURTHER ORDERED that summary judgment is GRANTED as to Counts I (to the extent it alleges a negligent manufacturing defect), II, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, and XV.

IT IS FURTHER ORDERED that summary judgment is DENIED as to Count I to the extent it alleges a negligent failure to warn claim and as to Count III.

IT IS FINALLY ORDERED that the parties shall submit a joint proposed case management order by April 3, 2020.

Dated this 16th day of March, 2020.

STEPHEN N. LIMBAUGH, JR.
UNITED STATES DISTRICT JUDGE